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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,124	06/16/2006	Aldo Giannozzi	PP019745.0003	6885
27476 7590 09/04/2009 NOVARTIS VACCINES AND DIAGNOSTICS INC. INTELLECTUAL PROPERTY- X100B P.O. BOX 8097 Emeryville, CA 94662-8097				
EXAMINER				
HENRY, MICHAEL C				
ART UNIT		PAPER NUMBER		
1623				
MAIL DATE		DELIVERY MODE		
09/04/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/526,124

**Applicant(s)**

GIANNOZZI ET AL.

**Examiner**

MICHAEL C. HENRY

**Art Unit**

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 6-45 and 47-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-3 and 8-45 is/are allowed.
- 6) ☒ Claim(s) 6, 7 and 47-50 is/are rejected.
- 7) ☒ Claim(s) 51 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The following office action is a responsive to the Amendment filed, 05/04/09.

The amendment filed 05/04/09 affects the application, 10/526,124 as follows:

1. Claims 1, 6, 10, 20, 33, 47, 48 have been amended. Claims 4 and 5 have been canceled. New Claim 51 has been added. Applicant's amendment has overcome the rejections made under 35 U.S.C. 102(b). Consequently, the said rejections are withdrawn. However, a new ground(s) of rejection is made herein.
2. The responsive to applicants' arguments is contained herein below.

Claims 1-3, 6-45, 47-51 are pending in application

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite since it omits the formula represented as formula (I). That is, the formula represented as formula (I) in the claim is not known.

#### ***Claim Rejections - 35 USC § 102***


The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –


(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6, 47-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Fu et al. (Gaodeng Xuexiao Huaxue Xuebao (1997), 18(7), 1071-1079, Abstract Only).


Claim 6 is drawn to a modified capsular saccharide wherein: A is a bond, -C(O)- or -OC(O)- R<sup>1</sup> is selected from H or C<sub>1</sub>-C<sub>6</sub> alkyl; L is -CH<sub>2</sub>CH<sub>2</sub>CH<sub>2</sub>-; M is a masked aldehyde selected from specific groups. Fu et al. disclose applicant's saccharide wherein A is a bond; R<sup>1</sup>

is H, L is a C<sub>2</sub> alkylene group and M is a masked aldehyde group,  (see abstract). Fu et al.'s saccharide has the Cas # 193979-23-6 (see abstract).


Claim 47 is drawn to a modified capsular saccharide comprising a moiety of the formula (I): -A-N(R<sup>1</sup>)-L-M, (I) wherein: A is a bond, -C(O)- or -OC(O)- R<sup>1</sup> is selected from H or C<sub>1</sub>-C<sub>6</sub> alkyl; L is a C<sub>1</sub>-C<sub>12</sub> alkylene group; M is a masked aldehyde group selected from specific groups. Fu et al. disclose applicant's saccharide of the formula (I) wherein A is a bond; R<sup>1</sup> is H, L is a C<sub>2</sub>

alkylene group and M is a masked aldehyde group,  (see abstract). Fu et al.'s saccharide has the Cas # 193979-23-6 (see abstract).

Claim 48 is drawn to a modified capsular saccharide comprising a moiety of the formula (I): -A-N(R<sup>1</sup>)-L-M, (I) wherein: A is a bond, -C(O)- or -OC(O)- R<sup>1</sup> is selected from H or C<sub>1</sub>-C<sub>6</sub> alkyl; L is a C<sub>1</sub>-C<sub>6</sub> alkylene group; M is a masked aldehyde group selected from specific groups. Fu et al. disclose applicant's saccharide of the formula (I) wherein A is a bond; R<sup>1</sup> is H, L is a C<sub>2</sub>


alkylene group and M is a masked aldehyde group,  (see abstract). Fu et al.'s saccharide has the Cas # 193979-23-6 (see abstract).

Claim 49 is also anticipated by Fu et al, since Fu et al's disclose applicant's saccharide of the formula (I) wherein A is a bond; R<sup>1</sup> is H, L is a C<sub>2</sub> alkylene group and M is a masked


aldehyde group,  (see abstract). Fu et al.'s saccharide has the Cas # 193979-23-6 (see abstract).

Claims 6, 47-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Cherif et al (Bioorganic & Medicinal Chemistry Letters (2002), 12(9), 1237-1240, Abstract Only).


Claim 6 is drawn to a modified capsular saccharide wherein: A is a bond, -C(O)- or -OC(O)- R<sup>1</sup> is selected from H or C<sub>1</sub>-C<sub>6</sub> alkyl; L is -CH<sub>2</sub>CH<sub>2</sub>CH<sub>2</sub>-; M is a masked aldehyde selected from specific groups. Cherif et al. disclose applicant's saccharide wherein A is -OC(O)-

; R<sup>1</sup> is H, L is a C<sub>1</sub> alkylene group and M is a masked aldehyde group,  (see abstract). Cherif et al.'s saccharide has the Cas # 459810-31-2 (see abstract).


Claim 47 is drawn to a modified capsular saccharide comprising a moiety of the formula (I): -A-N(R<sup>1</sup>)-L-M, (I) wherein: A is a bond, -C(O)- or -OC(O)- R<sup>1</sup> is selected from H or C<sub>1</sub>-C<sub>6</sub> alkyl; L is a C<sub>1</sub>-C<sub>12</sub> alkylene group; M is a masked aldehyde group selected from specific groups. Cherif et al. disclose applicant's saccharide of the formula (I) wherein A is -OC(O)-; R<sup>1</sup> is

H, L is a C<sub>1</sub> alkylene group and M is a masked aldehyde group,  (see abstract). Cherif et al.'s saccharide has the Cas # 459810-31-2 (see abstract).

Claim 48 is drawn to a modified capsular saccharide comprising a moiety of the formula (I):  $-A-N(R^1)-L-M$ , (I) wherein: A is a bond,  $-C(O)-$  or  $-OC(O)-$ ;  $R^1$  is selected from H or  $C_1-C_6$  alkyl; L is a  $C_1-C_6$  alkylene group; M is a masked aldehyde group selected from specific groups. Cherif et al. disclose applicant's saccharide of the formula (I) wherein A is  $-OC(O)-$ ;  $R^1$  is

H, L is a  $C_1$  alkylene group and M is a masked aldehyde group,  (see abstract). Cherif et al.'s saccharide has the Cas # 459810-31-2 (see abstract).

Claims 49 and 50 are also anticipated by Cherif et al, since Cherif et al.'s disclose applicant's saccharide of the formula (I) wherein A is  $-OC(O)-$ ;  $R^1$  is H, L is a  $C_1$  alkylene group

and M is a masked aldehyde group,  (see abstract). Cherif et al.'s saccharide has the Cas # 459810-31-2 (see abstract).

#### ***Allowable Subject Matter***

Claim 51 is objected to as being dependent upon a rejected base claim, but may be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The examiner has found claims 1, 2, 3, 8-45 to be unobvious over the prior art of record and may therefore be allowable over the prior art of record. Claims 1, 2, 3, 8-45 are drawn to specific modified capsular oligosaccharide or polysaccharide, conjugates, and a method of modifying and using said compounds. The prior art does not teach or suggest the specific modified capsular oligosaccharide or polysaccharide, conjugates or the method of modifying and using said compounds as set forth in said claims.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 6, 7, and 47-50 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry  
August 16, 2009.

/Shaojia Anna Jiang/  
Supervisory Patent Examiner  
Art Unit 1623